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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/453,350	05/30/95	HELDIN C	0054.009

HM22/0222

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INTELLECTUAL PROPERTY R440
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EXAMINER	
SAOUD, C	
ART UNIT	**PAPER NUMBER**
1646	45

DATE MAILED: 02/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
08/453,350	HELDIN et al.
Examiner	**Group Art Unit**
Christine Saoud	1646

☒ Responsive to communication(s) filed on *Dec 8, 1999* .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *25-27 and 43-66* is/are pending in the application.

Of the above, claim(s) *46-54* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *25-27, 43-45, and 55-66* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Amendment

1. Claims 25-27 and 43-66 are pending in the instant application. Claims 46-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention (see paper #31, paragraph #3).

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed 08 December 1999 have been fully considered but they are not deemed to be persuasive.

Claim Rejections - 35 USC § 102

5. Claims 25-27, 43-45, and 55-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Heldin et al. (Nature 319: 511-514, 1986) for the reasons of record in paper #31 as applied to claims 25-27 and 43-45.

Applicant argues that "Heldin fails to expressly or inherently disclose a protein preparation produced recombinantly from nonhuman cells". However, the limitation of recombinantly produced from nonhuman cells is a product by process limitation. Patentability depends on whether the product is known in the art or obvious, and is not governed by its process of production (In re Klug, 142 USPQ 161); therefore, the burden is upon applicants to establish a patentable difference (In re Fessman, 180 USPQ 324). Further held was that when a prior art product reasonably appears to be the same as the claimed, but differs by process in which it was produced, a rejection of this nature is eminently fair and the burden is upon appellants to prove, by comparative evidence, a patentable difference (In re Brown, 173 USPQ 685; In re Marosi, 218 USPQ 289; In re Thorpe, 227 USPQ 965; In re Fitzgerald, 205 USPQ 594; and as more recently emphasized in Ex parte Gray, 10 USPQ2d 1922; Amgen Inc. v. Chugai Pharmaceutical Co., 9 USPQ2d 1822; and Scripps Clinic v. Genentech Inc., 3 USPQ2d 1481). Furthermore, in a recent court decision regarding proteins, the decisional law held that recombinantly produced proteins are not patentable or functionally distinct from their native counterpart proteins (Ex parte Gray, 10 USPQ2d 1922; Amgen Inc. v. Chugai, 9 USPQ2d 1833; and Scripps v. Genentech, 3 USPQ2d 1481). In view of the fact that the courts have clearly emphasized that product claims unless there has been established a patentable difference, one having ordinary skill in the art at the time of the invention would have expected that the PDGF produced by the recombinant process of the instant

claims would be functionally/biologically equivalent to native PDGF as produced by Heldin and would therefore function in a manner taught by the prior art.

Applicant argues that Heldin's protein preparation is not free of other human proteins. Applicant has not offered any comparative evidence to support this conclusion. Additionally, Applicant is applying absolutes which are not possible in any preparation, be it from a tissue source or from recombinant production of a protein. This is because in any protein preparation, there will always be trace amounts of human proteins, even if they come from handling of the labware which is used in making the protein. Applicant's standard of "free of other human proteins" is an unattainable standard which cannot even be met by Applicant's recombinant methods of production. The evidence which supports a pure preparation of PDGF of the prior art is that (1) the protein of Heldin appeared to be homogeneous due to a single band on a silver-stained gel, (2) Heldin's statement that one homogeneous component was obtained, and (3) that no other amino acid sequences were obtained from the purified protein preparation. Based on Applicant's standard of "free of human protein contaminants", there is no preparation in existence that would meet this standard. According to the facts of record, there is no evidence to support a conclusion that there were any other proteins present in the preparation of Heldin et al. and no evidence of any other protein present has bee provided by Applicant. The courts have held that when a prior art product reasonably appears to be the same as the claimed, but differs by process in which it was produced, a rejection of this nature is eminently fair and the burden is upon appellants to prove, by comparative evidence, a patentable difference.

Claim Rejections - 35 USC § 103

6. Claims 55-57 are rejected under 35 U.S.C. 103(a) as obvious over Heldin et al.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant argues that there is no suggestion in the reference to use recombinant methods or obtain a protein that is free of other human proteins. These arguments were addressed above in the 102 rejection. Applicant asserts that recombinantly produced proteins are not necessarily obvious over the same proteins produced from natural sources. This point is not disputed, however, the facts of record in the instant application support a conclusion that the PDGF preparation of Heldin is not different from that which is claimed, and therefore, the PDGF composition is anticipated, and pharmaceutical compositions would have been prima facie obvious for the reasons of record in paper #42. Applicant has not addressed the obviousness of the pharmaceutical compositions, but rather is arguing the nature of the isolated PDGF. These arguments were previously presented and answered above

Conclusion

7. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 3PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christine Saoud, Ph.D.
February 17, 2000
Christine Saoud

JOHN ULM
PRIMARY EXAMINER
GROUP 1800